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REMARKS

Claims 1, 2, 6, 8, 9, 29, and 30 are pending and under consideration in the subject application.

Sequence Listing

The Examiner indicated that the subject application does not comply with the requirements of 37 C.F.R. §§1.821-1.825 for the reasons set forth on the Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures that was enclosed with the December 16, 2003 Office Action. A copy of the Notice is attached hereto as **Exhibit 2**.

Applicants have hereinabove amended the specification to provide a Sequence Listing for the peptide sequences set forth on page 16 of the application. Applicants maintain that the amendments to the specification do not raise an issue of new matter. Accordingly, applicants respectfully request that the amendments be entered.

A paper copy of a Sequence Listing is provided as **Exhibit 1** (1 page) and a computer readable form of the Sequence Listing on a floppy disk is attached hereto. Pursuant to 37 C.F.R. §1.821(f), the Sequence Listing information recorded in computer readable form and filed herewith is identical to the paper copy of the Sequence Listing attached hereto as Exhibit 1.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this objection regarding sequence disclosures.

Declaration

The Examiner indicated that the Declaration is defective because the signature of inventor Irene Wapnir has no date.

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Applicants note that a Supplemental Declaration, signed and dated by Irene Wapnir, was filed in connection with the subject application on November 29, 2000. A copy of the previously submitted Declaration signed and dated by Irene Wapnir is attached hereto as **Exhibit 3**.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this objection regarding the Declaration.

Rejections regarding "mgNIS" under 35 U.S.C. §112, First and Second Paragraphs

The pending claims are rejected as indefinite under 35 U.S.C. §112, second paragraph, because claims 1 and 30 recite "mgNIS." The Examiner indicated that mgNIS is a laboratory designation coined by the inventors and unknown to the public at the time of filing and that the metes and bounds of what constitutes mgNIS versus human thyroid NIS is unknown and not set forth in the specification.

The pending claims are also rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner stated in part that the specification does not provide an adequate written description of mgNIS required to practice the claimed invention.

Applicants respectfully traverse these rejections.

Applicants note that claims 1 and 30 define "mgNIS" as a abbreviation for "mammary gland sodium/iodide symporter."

Applicants also note that the specification on page 23, lines 3-5, states that "[t]hese findings are consistent with the recently reported full identity between cDNAs that encode the human thyroid and mammary NIS proteins (Spitzweg *et al.*, 1998)." The full citation for Spitzweg et al. is given in the specification on page 44, lines 22-25. Spitzweg et al. is incorporated by reference into the application (see specification, page 45, line 34-35). Spitzweg et al. (1998) is a reference of record in the subject application. Applicants

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further note that Spitzweg et al. state in the Abstract that “[t]he nucleotide sequences of hNIS cDNA derived from parotid gland, mammary gland, and gastric mucosa revealed full identity with the recently published human thyroid-derived NIS cDNA sequence.” See also the Results section spanning pages 1748-49 of Spitzweg et al. where the human thyroid-derived NIS cDNA is referenced as described in Smanik et al., 1996. The subject application states on page 11, lines 5-6, that “[t]he nucleotide sequences for both rat and human NIS are known (Dai *et al.*, 1996a; and Smanik *et al.*, 1996).” The full citation for Smanik et al. 1996 is listed on page 44, lines 19-20, of the specification. Smanik et al. (1996) is incorporated by reference into the application (see specification, page 45, line 34-35).

Applicants maintain that one skilled in the art would readily understand the metes and bounds of the claimed invention. Furthermore, applicants maintain that the description in the specification would reasonably convey to one skilled in the art that the inventors were in possession of the claimed invention at the time the subject application was filed. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw these grounds of rejection.

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CONCLUSIONS


In light of the above amendments and remarks, applicants respectfully request withdrawal of the objections and rejections set forth in the December 16, 2003 Office Action and passage of pending claims 1, 2, 6, 8, 9, 29, and 30 to allowance. If there are any minor matters that would prevent allowance of the claims, applicants request that the Examiner telephone the undersigned attorney.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required to preserve the pendency of the subject application, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 01-1785.

Respectfully submitted,

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